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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,806	12/01/2003	Randy D. Blakely	VBLT:008USD1	3686

7590 08/09/2006

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EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/724,806	BLAKELY ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/5/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Appendices A, B, C, D*

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 01 December 2003 has been entered in full. Claims 1-28 and 37-105 are cancelled.

Claims 29-36 are under consideration in the instant application.

Information Disclosure Statement

The information disclosure statement filed 05 March 2004 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language (document DE 10009055). It has been placed in the application file, but the information referred to therein has not been considered.

Sequence Compliance

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). **Specifically, the sequences disclosed in Figure 2 and Figure 4 are not accompanied by the required reference to the relevant sequence identifiers.** This application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825).

Claim Objections

2. Claim 29 is objected to because of the following informalities:

2a. In claim 29, line 1 is missing the term "acid" after "amino". Appropriate correction is required.

Specification

3. The disclosure is objected to because of the following informalities:

3a. Patent applications are referenced throughout the disclosure (for example, pg 136, line 22). The status of the applications must be updated.

3b. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (See for example, pg 20, line 20; pg 25, line 17; pg 46, line 24). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

3c. The Brief Description of Drawings for Figure 11 at pg 10-11 of the specification does not refer to Figures 11C or 11D.

3d. The Brief Description of Drawings for Figure 14 at pg 11 of the specification does not refer to Figures 14A and 14B.

3e. The reference cited at pg 3, line 10 (Apparsundaram 2001) needs to updated as it is still listed as "in press".

3f. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "POLYNUCLEOTIDE ENCODING A MURINE CHOLINE TRANSPORTER".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 29-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding a polypeptide comprising the amino acid sequence as set forth in SEQ ID NO: 4 and for an isolated polynucleotide comprising the nucleic acid sequence as set forth in SEQ ID NO: 3, does not reasonably provide enablement for an isolated polynucleotide encoding a polypeptide comprising the amino acid sequence essentially as set forth in SEQ ID NO: 4 or for an isolated polynucleotide comprising the nucleic acid sequence essentially as set forth in SEQ ID NO: 3. The specification is also not enabling for a purified and isolated polynucleotide comprising a sequence identical or complementary to between 10 and 100 contiguous nucleotides of SEQ ID NO: 3. The specification is also not enabling for a recombinant vector or recombinant host cell comprising a DNA segment encoding any isolated murine choline transporter. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is noted that the phrases "comprising/having ...essentially as set forth in SEQ ID NO:", "an isolated choline transporter" (for example, claim 34), and "(c)DNA segment" as recited in the claims, are broadly interpreted by the Examiner as reading upon: (i) nucleic acid variants of SEQ ID NO: 3 with any number of deletions, substitutions, or additions and (ii) protein variants of SEQ ID NO: 4 with any number of deletions, substitutions, or additions.

Specifically, the claims are directed to an isolated polynucleotide encoding a polypeptide comprising the amino acid sequence essentially as set forth in SEQ ID NO: 4 and an isolated polynucleotide comprising the nucleic acid sequence essentially as set forth in SEQ ID NO: 3. The claims also recite a purified and isolated polynucleotide comprising a sequence identical or complementary to between 10 and 100 contiguous nucleotides of SEQ ID NO: 3. The claims recite that the polynucleotide is comprising in a vector. The claims also recite a recombinant vector comprising a DNA segment encoding a mouse choline transporter polypeptide under the control of a promoter.

The specification of the instant application teaches that nucleic acid variants may be any length and that "a DNA segment encoding CHT refers to a DNA segment that contains wild-type, polymorphic or mutant CHT coding sequences yet is isolated away from, or purified free from, total mammalian genomic DNA. Included within the term "DNA segment," are DNA segments and smaller fragments of such segments, and also recombinant vectors, including, for example, plasmids, cosmids, phage, viruses, and the like" (pg 23, lines 7-12; pg 30; pg 42). The specification teaches only teaches a murine CHT polynucleotide and polypeptide of SEQ ID NO: 3 and SEQ ID NO: 4, respectively. The specification does not teach any variants, fragments, or derivatives of the nucleic acid sequence of SEQ ID NO: 3. The specification does not teach any variants, fragments, or derivatives of a polynucleotide that encodes the polypeptide of SEQ ID NO: 4. The specification also does not teach all possible DNA segments that encode an isolated murine choline transporter. Further, the specification does not teach functional or structural characteristics of the polynucleotide variants, fragments, or derivatives in the context of a cell or organism.

The problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the DNA and amino acid sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells, 1990, Biochemistry 29:8509-8517; Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495). For example, Okuda et al. (J Biol Chem 277(47): 45315-45322, 2002) teach that a single amino acid change from an isoleucine to a valine at amino acid position 89 in the human choline transporter causes a 40-50% decrease in choline uptake as compared with wild-type (pg 45317, col 2, ¶ 2; pg 45319, col 1-2; Figure 3, Table II, Figure 6B, C). Okuda et al. also demonstrate that introduction of an isoleucine in place of valine at corresponding amino acid position 90 in the *C. elgans* ortholog (CHO-1) also causes a 40% decrease in choline uptake with unaltered affinity for choline (pg 45319, col 2 through pg 45320, col 1; Figure 6D, E).

However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the DNA and protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made

in these positions. Although the specification outlines art-recognized procedures for producing and screening for active muteins, this is not adequate guidance as to the nature of active derivatives that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. The art recognizes that function cannot be predicted from structure alone (Bork, 2000, Genome Research 10:398-400; Skolnick et al., 2000, Trends in Biotech. 18(1):34-39, especially p. 36 at Box 2; Doerks et al., 1998, Trends in Genetics 14:248-250; Smith et al., 1997, Nature Biotechnology 15:1222-1223; Brenner, 1999, Trends in Genetics 15:132-133; Bork et al., 1996, Trends in Genetics 12:425-427).

Additionally, the Examiner has interpreted claims 89-91 as reading on isolated host cells, as well as host cells in the context of a multicellular, transgenic organism and host cells intended for gene therapy. The specification of the instant application teaches that CHT gene product can be expressed in transgenic animals (for example pg 7, lines 28-29; pg 8, lines 1-8). However, there are no methods or working examples disclosed in the instant application whereby a multicellular animal with the incorporated mCHT gene of SEQ ID NO: 3 is demonstrated to express the mCHT polypeptide. The unpredictability of the art is *very high* with regards to making transgenic animals. For example, Wang et al. (Nuc. Acids Res. 27: 4609-4618, 1999; pg 4617) surveyed gene expression in transgenic animals and found in each experimental animal

with a single "knock-in" gene, multiple changes in genes and protein products, often many of which were unrelated to the original gene. Likewise, Kaufman et al (Blood 94: 3178-3184, 1999) found transgene expression levels in their transfected animals varied from "full" (9 %) to "intermediate" to "none" due to factors such as "vector poisoning" and spontaneous structural rearrangements (pg 3180, col 1, 2nd full paragraph; pg 3182-3183). Therefore, , it would have required undue experimentation for the skilled artisan to have made any and all transgenic non-human animals according to the instant invention.

The specification also discloses that nucleic acids encoding the mCHT polypeptide can be used for gene therapy (pg 3, line 22). However, the specification does not teach any methods or working examples that indicate a mCHT nucleic acid is introduced and expressed in a cell for therapeutic purposes. The disclosure in the specification is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. For example, the specification does not teach what type of vector would introduce the mCHT nucleic acid into the cell or in what quantity and duration. Relevant literature teaches that since 1990, about 3500 patients have been treated via gene therapy and although some evidence of gene transfer has been seen, it has generally been inadequate for a meaningful clinical response (Phillips, A., J Pharm Pharmacology 53: 1169-1174, 2001; abstract). Additionally, the major challenge to gene therapy is to deliver DNA to the target tissues and to transport it to the cell nucleus to enable the required protein to be expressed (Phillips, A.; pg 1170, ¶ 1). Phillips also states that the problem with gene therapy is two-fold: 1) a system must designed to deliver DNA to a specific target and to prevent degradation within the body, and 2) an expression system must be built into the DNA construct to allow the target cell to express the protein at therapeutic levels for the desired length

of time (pg 1170, ¶ 1). Therefore, undue experimentation would be required of the skilled artisan to introduce and express a mCHT nucleic acid into the cell of an organism. Additionally, gene therapy is unpredictable and complex wherein one skilled in the art may not necessarily be able to introduce and express a mCHT nucleic acid in the cell of an organism or be able to produce a mCHT protein in that cell. (Please note that this issue could be overcome by amending the claims to recite, for example, "An isolated host cell...").

Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen the same for activity, and to generate a transgenic animal expressing the mCHT protein and to introduce and express a mCHT nucleic acid in a cell of an organism for therapy; the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity and how to introduce a mCHT nucleic acid in the cell of an organism to be able produce that mCHT; the absence of working examples directed to same; the complex nature of the invention; the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function and the unpredictability of making transgenic animals and of transferring genes into an organism's cells; and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

5. Claims 29-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the claims are directed to an isolated polynucleotide encoding a polypeptide comprising the amino acid sequence essentially as set forth in SEQ ID NO: 4 and an isolated polynucleotide comprising the nucleic acid sequence essentially as set forth in SEQ ID NO: 3. The claims also recite a purified and isolated polynucleotide comprising a sequence identical or complementary to between 10 and 100 contiguous nucleotides of SEQ ID NO: 3. The claims recite that the polynucleotide is comprising in a vector. The claims also recite a recombinant vector comprising a DNA segment encoding a mouse choline transporter polypeptide under the control of a promoter.

It is noted that the phrases "comprising/having ...essentially as set forth in SEQ ID NO:", "an isolated choline transporter" (for example, claim 34), and "(c)DNA segment" as recited in the claims, are broadly interpreted by the Examiner as reading upon: (i) nucleic acid variants of SEQ ID NO: 3 with any number of deletions, substitutions, or additions and (ii) protein variants of SEQ ID NO: 4 with any number of deletions, substitutions, or additions.

The specification of the instant application teaches that nucleic acid variants may be any length and that "a DNA segment encoding CHT refers to a DNA segment that contains wild-type, polymorphic or mutant CHT coding sequences yet is isolated away from, or purified free from, total mammalian genomic DNA. Included within the term "DNA segment," are DNA segments and smaller fragments of such segments, and also recombinant vectors, including, for example, plasmids, cosmids, phage, viruses, and the like" (pg 23, lines 7-12; pg 30; pg 42). However, the claims do not require that the nucleic acid or polypeptide possess any particular

biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of nucleic acid molecules.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, there is not even identification of any particular portion of the nucleic acid structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Additionally, the description of one mCHT polynucleotide species (SEQ ID NO: 3) and one mCHT polypeptide species (SEQ ID NO: 4) is not adequate written description of an entire genus of functionally equivalent polynucleotides and polypeptides which incorporate all variants, fragments, and derivatives of SEQ ID NO: 3 and SEQ ID NO: 4.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is

not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated nucleic acid molecule consisting of the nucleic acid sequence of SEQ ID NO:3 and a nucleic acid molecule which encodes a polypeptide consisting of the amino acid sequence of SEQ ID NO:4, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 29-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 29-34 are rejected as being indefinite because the claims fail to define the metes and bounds of the phrase "comprising/having...essentially as set forth in SEQ ID NO:". For example, it is not clear if this language is open or closed or what polynucleotides/polypeptides are encompassed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 29-34 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Okuda et al. (Nat Neurosci 3(2): 120-125, 2000; Genbank Accession No. AB030947). It is noted that the phrase "comprising/having ...essentially as set forth in SEQ ID NO:", as recited in the claims, is broadly interpreted by the Examiner as reading upon: (i) nucleic acid variants of SEQ ID NO: 3 with any number of deletions, substitutions, or additions and (ii) protein variants of SEQ ID NO: 4 with any number of deletions, substitutions, or additions.

Okuda et al. teach an isolated "CHT1" polynucleotide that is 92.7% identical to the nucleic acid sequence of SEQ ID NO: 3 of the instant application (see sequence alignment attached to the instant Office Action as Appendix A). The CHT1 polynucleotide of Okuda et al. comprises a nucleic acid sequence that is identical to at least 134 contiguous nucleotides of SEQ ID NO: 3 of the instant application (see nucleic acids 1418-1551 of Okuda et al. and nucleic

acids 1195-1328 of SEQ ID NO:3 of the instant application). Okuda et al. also disclose that the CHT1 polynucleotide encodes a choline transporter polypeptide (see sequence alignment attached to the instant Office Action as Appendix B; see Figure 2a of Okuda et al.) Okuda et al. teach that the CHT1 cDNA is isolated and subcloned into the pcDNA3.1+ vector, which contains a cytomegalovirus immediate early (CMV) promoter/enhancer (pg 124, 2nd full paragraph). Okuda et al. disclose transfecting COS7 cells with the CHT1/pcDNA3.1+ vector (pg 124, Figure 5).

9. Claims 29-36 are rejected under 35 U.S.C. 102(a) as being anticipated by Haga et al. (WO 0116315; 08 March 2001; see also pg 24-25 of CA 2382464 (Canadian translation of WO 0116315)).

Haga et al. teach an isolated murine polynucleotide that is 99.3% identical to the nucleic acid sequence of SEQ ID NO: 3 of the instant application (see sequence alignment attached to the instant Office Action as Appendix C; see also SEQ ID NO: 7 of Haga et al.). The CHT1 polynucleotide of Haga et al. comprises a nucleic acid sequence that is identical to over 100 contiguous nucleotides of SEQ ID NO: 3 of the instant application (see nucleic acids 356-1733 of Haga et al. and nucleic acids 356-1733 of SEQ ID NO:3 of the instant application). Haga et al. also disclose that the CHT1 polynucleotide encodes a choline transporter polypeptide (see sequence alignment attached to the instant Office Action as Appendix D; see SEQ ID NO: 8 of Haga et al.) Haga et al. teach that the gene encoding the mCHT protein may be introduced into a host cell by a number of different methods (pg 22, lines 13-26). Haga et al. teach that vectors

may used as an expression system to express the protein in a host cell and that the vectors may contain a regulatory sequence that acts as a promoter (pg 23, lines 7-17).

Conclusion

No claims are allowable.

The art made of record and not relied upon is considered pertinent to applicant's disclosure:

Wu et al. (U.S. Patent 6,500,643) (SEQ ID NO : 1 of Wu et al. is 79.1% identical to SEQ ID NO: 3 of the instant application)

Invitrogen 2001 catalog, pg 155 (pcDNA vectors)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB
Art Unit 1647
04 August 2006

Bridget E. Bunner

BRIDGET BUNNER
PATENT EXAMINER

```
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Db       1501 CTATTTGAAAGTGGAACCTTGCCTCCAAAATTAGATATATTTGATGCTGTTGTCTCAAGG 1560

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ACCESSION   AB030947
VERSION     AB030947.1  GI:6863033
KEYWORDS    choline transporter; high-affinity choline transporter CHT1.
SOURCE      Rattus norvegicus (Norway rat)
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            Sciurognathi; Muroidea; Muridae; Murinae; Rattus.
REFERENCE   1  (sites)
  AUTHORS   Okuda,T., Haga,T., Kanai,Y., Endou,H., Ishihara,T. and Katsura,I.
  TITLE     Identification and characterization of the high-affinity choline
            transporter
  JOURNAL   Nat. Neurosci. 3 (2), 120-125 (2000)
  PUBMED    10649566
REFERENCE   2  (bases 1 to 4904)
  AUTHORS   Okuda,T.
  TITLE     Direct Submission
  JOURNAL   Submitted (09-AUG-1999) Takashi Okuda, University of Tokyo, Faculty
            of Medicine, Department of Neurochemistry; Hongo 7-3-1, Bunkyo-ku
            113-0033, Japan (E-mail:okuda@m.u-tokyo.ac.jp, Tel:+81-3-5841-3560,
            Fax:+81-3-3814-8154)
COMMENT     Sequence updated (11-Jan-2000).
FEATURES             Location/Qualifiers
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Db        344 GCCATCATAGTTGGGGGCCGAGACATTGGTTTGTTGGTTGGTGGTTTTACCATGACAGCC 403

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Qy      1621 GAACTTGCACCTGTGAAACCTCGGCAGAGCCTAACCCTCAGTTCAACTTTCACCAATAAG 1680
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Qy      1741 TGA 1743
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LOCUS       AR268949                1743 bp    DNA     linear   PAT 10-APR-2003
DEFINITION  Sequence 1 from patent US 6500643.
ACCESSION   AR268949
VERSION     AR268949.1  GI:29699686
KEYWORDS    .
SOURCE      Unknown.
  ORGANISM  Unknown.
            Unclassified.
REFERENCE   1  (bases 1 to 1743)
  AUTHORS   Wu,D.-H., Gu,Y., Millard,W.J. and He,Y.-J.
  TITLE     Human high affinity choline transporter
  JOURNAL   Patent: US 6500643-A 1 31-DEC-2002;
            University of Florida; Gainesville, FL
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Query Match 79.1%; Score 1378.2; DB 2; Length 1743;
Best Local Similarity 86.9%; Pred. No. 0;
Matches 1515; Conservative 0; Mismatches 228; Indels 0; Gaps 0;

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Appendix B

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DEFINITION Rattus norvegicus mRNA for high-affinity choline transporter CHT1, complete cds.
ACCESSION AB030947
VERSION AB030947.1 GI:6863033
KEYWORDS choline transporter; high-affinity choline transporter CHT1.
SOURCE Rattus norvegicus (Norway rat)
ORGANISM Rattus norvegicus
Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Euarchontoglires; Glires; Rodentia; Sciurognathi; Muroidea; Muridae; Murinae; Rattus.
REFERENCE 1 (sites)
AUTHORS Okuda,T., Haga,T., Kanai,Y., Endou,H., Ishihara,T. and Katsura,I.
TITLE Identification and characterization of the high-affinity choline transporter
JOURNAL Nat. Neurosci. 3 (2), 120-125 (2000)
PUBMED 10649566
REFERENCE 2 (bases 1 to 4904)
AUTHORS Okuda,T.
TITLE Direct Submission
JOURNAL Submitted (09-AUG-1999) Takashi Okuda, University of Tokyo, Faculty of Medicine, Department of Neurochemistry; Hongo 7-3-1, Bunkyo-ku 113-0033, Japan (E-mail:okuda@m.u-tokyo.ac.jp, Tel:+81-3-5841-3560, Fax:+81-3-3814-8154)
COMMENT Sequence updated (11-Jan-2000).

FEATURES Location/Qualifiers
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ORIGIN

Alignment Scores:

Pred. No.:	0	Length:	4904
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Best Local Similarity:	98.6%	Mismatches:	4
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US-10-724-806-4 (1-580) x AB030947 (1-4904)

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Appendix B (cont.)

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RESULT 10
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LOCUS	BD012719	1743 bp DNA linear PAT 02-AUG-2002
DEFINITION	High-affinity choline transporter.	
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VERSION	BD012719.1 GI:22092908	
KEYWORDS	WO 0116315-A/3.	
SOURCE	Homo sapiens (human)	
ORGANISM	Homo sapiens	
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	Mammalia; Eutheria; Euarchontoglires; Primates; Catarrhini;	
	Hominidae; Homo.	
REFERENCE	1 (bases 1 to 1743)	
AUTHORS	Haga,T. and Okuda,T.	
TITLE	High-affinity choline transporter	
JOURNAL	Patent: WO 0116315-A 3 08-MAR-2001;	
	JAPAN SCIENCE AND TECHNOLOGY CORP,TATSUYA HAGA,TAKASHI OKUDA	
COMMENT	OS Homo sapiens (human)	
	PN WO 0116315-A/3	
	PD 08-MAR-2001	
	PF 18-AUG-2000 WO 2000JP005545	
	PR 27-AUG-1999 JP 99P 240642,27-DEC-1999 JP 99P 368991 PI	
	TATSUYA HAGA,TAKASHI OKUDA	
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	A61K38/17,	
	PC A61K45/00,A61P25/28,G01N33/53,A01K67/027	
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Percent Similarity:	96.6%	Conservative:	23
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US-10-724-806-4 (1-580) x BD012719 (1-1743)

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Qy         21 ValGlyIleTrpAlaAlaTrpLysThrLysAsnSerGlyAsnProGluGluArgSerGlu 40
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Appendix C

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Qy       1081 CGGAATATCTACCAGCTTTCCTTCAGACAAAATGCATCAGACAAGGAAATTGTGTGGGTC 1140
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Qy       1141 ATGAGGATCACTGTGCTTGTGTTCGGAGCATCTGCAACAGCCATGGCTTTGCTGACGAAG 1200
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Qy       1261 CTGCTCTGTGTACTCTTCATCAAAGGAACCAACACTTATGGGGCAGTTGCTGGTTATATT 1320
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Db       1287 CTGCTCTGTGTACTCTTCATCAAAGGAACCAACACTTATGGGGCAGTTGCTGGTTATATT 1346

Qy       1321 TTTGGACTATTCCTGAGAATTACTGGAGGAGAGCCATATCTATACTTGCAGCCCTTAATC 1380
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Qy       1381 TTCTACCCTGGTTATTACTCTGACAAGAATGGTATATACAATCAGAGGTTCCCATTTAAA 1440
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Qy       1441 ACTCTCTCCATGGTTACCTCATTCTTTACCAACATTTGTGTTTCTTATCTAGCCAAGTAT 1500
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Qy       1741 TGA 1743
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DEFINITION  High-affinity choline transporter.
ACCESSION   BD012720
VERSION     BD012720.1  GI:22092909
KEYWORDS    WO 0116315-A/4.
SOURCE      Mus musculus (house mouse)
  ORGANISM  Mus musculus
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Mammalia; Eutheria; Euarchontoglires; Glires; Rodentia;
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REFERENCE   1  (bases 1 to 1743)
  AUTHORS   Haga,T. and Okuda,T.
  TITLE     High-affinity choline transporter
  JOURNAL   Patent: WO 0116315-A 4 08-MAR-2001;
            JAPAN SCIENCE AND TECHNOLOGY CORP,TATSUYA HAGA,TAKASHI OKUDA
COMMENT     OS   Mus musculus (mouse)
            PN   WO 0116315-A/4
            PD   08-MAR-2001
            PF   18-AUG-2000 WO 2000JP005545
            PR   27-AUG-1999 JP 99P   240642,27-DEC-1999 JP 99P   368991 PI
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ORIGIN

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DEFINITION  High-affinity choline transporter.
ACCESSION   E49872
VERSION     E49872.1  GI:22554903
KEYWORDS    JP 2001136976-A/4.
SOURCE      Mus sp.
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            Mammalia; Eutheria; Euarchontoglires; Glires; Rodentia;
            Sciurognathi; Muroidea; Muridae; Murinae; Mus
REFERENCE   1  (bases 1 to 1743)
  AUTHORS   Haga,T. and Okuda,T.
  TITLE     High-affinity choline transporter
  JOURNAL   Patent: JP 2001136976-A 4 22-MAY-2001;
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COMMENT     OS   Mus sp. (mouse)
            PN   JP 2001136976-A/4
            PD   22-MAY-2001
            PF   27-DEC-1999 JP 1999368991
            PI   TATSUYA HAGA,TAKASHI OKUDA
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Qy        201 IleSerValProPheAlaLeuSerHisProAlaValThrAspIleGlyPheThrAlaVal 220
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Db       1647 GAACTTGCACCTGTGAAACCTCGGCAGAGCCTAACCCTCAGTTCAACTTTCACCAATAAG 1706
Qy        561 GluAlaLeuLeuAspValAspSerSerProGluGlySerGlyThrGluAspAsnLeuGln 580
Db       1707 GAGGCCCTCCTTGATGTTGATTCCAGTCCGGAGGGGTCTGGGACTGAAGATAACTTACAA 1766
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RESULT 3
BD012720

LOCUS	BD012720 1743 bp DNA linear PAT 02-AUG-2002
DEFINITION	High-affinity choline transporter.
ACCESSION	BD012720
VERSION	BD012720.1 GI:22092909
KEYWORDS	WO 0116315-A/4.
SOURCE	Mus musculus (house mouse)
ORGANISM	Mus musculus Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Euarchontoglires; Glires; Rodentia; Sciurognathi; Muroidea; Muridae; Murinae; Mus.
REFERENCE	1 (bases 1 to 1743)
AUTHORS	Haga,T. and Okuda,T.
TITLE	High-affinity choline transporter
JOURNAL	Patent: WO 0116315-A 4 08-MAR-2001; JAPAN SCIENCE AND TECHNOLOGY CORP,TATSUYA HAGA,TAKASHI OKUDA
COMMENT	OS Mus musculus (mouse) PN WO 0116315-A/4 PD 08-MAR-2001 PF 18-AUG-2000 WO 2000JP005545 PR 27-AUG-1999 JP 99P 240642,27-DEC-1999 JP 99P 368991 PI TATSUYA HAGA,TAKASHI OKUDA PC C12N15/12,C07K14/47,C12Q1/68,C07K19/00,C07K16/18,C12N5/10, PC A61K38/17, PC A61K45/00,A61P25/28,G01N33/53,A01K67/027 CC FH Key Location/Qualifiers FT CDS (1). .(1743).
FEATURES	Location/Qualifiers source 1. .1743 /organism="Mus musculus" /mol_type="genomic DNA" /db_xref="taxon:10090"
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Alignment Scores:

Pred. No.:	0	Length:	1743
Score:	2968.00	Matches:	576
Percent Similarity:	99.5%	Conservative:	1
Best Local Similarity:	99.3%	Mismatches:	3
Query Match:	99.2%	Indels:	0
DB:	2	Gaps:	0

US-10-724-806-4 (1-580) x BD012720 (1-1743)

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Qy          1 MetProPheHisValGluGlyLeuValAlaIleIleLeuPheTyrLeuLeuIlePheLeu 20
Db          1 ATGTCTTTCCACGTAGAAGGACTGGTAGCTATTATCCTCTTCTACCTCCTTATATTTCTG 60
Qy         21 ValGlyIleTrpAlaAlaTrpLysThrLysAsnSerGlyAsnProGluGluArgSerGlu 40
Db         61 GTTGGAATATGGGCTGCATGGAAAACCAAAAACAGCGGCAACCCAGAAGAGCACAGTGAA 120
Qy         41 AlaIleIleValGlyGlyArgAspIleGlyLeuLeuValGlyGlyPheThrMetThrAla 60
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Db        121 GCCATCATAGTCGGGGGCCGTGACATTGGTTTGTTGGTTGGTGGTTTTACCATGACAGCC 180
Qy         61 ThrTrpValGlyGlyGlyTyrIleAsnGlyThrAlaGluAlaValTyrGlyProGlyCys  80
Db        181 ACCTGGGTTGGAGGAGGCTACATCAATGGGACAGCAGAAGCAGTGTATGGGCCAGGTTGT 240
Qy         81 GlyLeuAlaTrpAlaHisAlaProIleGlyTyrSerLeuSerLeuIleLeuGlyGlyLeu 100
Db        241 GGTCTAGCTTGGGCTCAGGCACCCATTGGATATTCTCTGAGTCTAATTTTAGGTGGTCTG 300
Qy        101 PhePheAlaLysProMetArgSerLysGlyTyrValThrMetLeuAspProPheLysGln 120
Db        301 TTTTTTGCGAAACCTATGCGTTCCAAGGGATATGTGACTATGTTAGACCCATTTCAACAG 360
Qy        121 IleTyrGlyLysArgMetGlyGlyLeuLeuPheIleProAlaLeuMetGlyGluMetPhe 140
Db        361 ATCTATGGAAAGCGCATGGGTGGGCTGCTCTTCATCCCTGCACTGATGGGAGAGATGTTC 420
Qy        141 TrpAlaAlaAlaIlePheSerAlaLeuGlyAlaThrIleSerValIleIleAspValAsp 160
Db        421 TGGGCTGCAGCAATTTTCTCTGCATTAGGGGCCACCATCAGCGTGATCATTGATGTGGAT 480
Qy        161 ValAsnIleSerValIleValSerAlaLeuIleAlaIleLeuTyrThrLeuValGlyGly 180
Db        481 GTGAACATATCGGTCATTGTCTCTGCACTCATTGCCATTCTTTATACCCTAGTGGGTGGG 540
Qy        181 LeuTyrSerValAlaTyrThrAspValValGlnLeuPheCysIlePheIleGlyLeuTrp 200
Db        541 CTCTACTCTGTGGCATATACTGATGTTGTCCAGCTATTCTGCATTTTTATAGGACTGTGG 600
Qy        201 IleSerValProPheAlaLeuSerHisProAlaValThrAspIleGlyPheThrAlaVal 220
Db        601 ATCAGTGTCCCTTTTGCCCTGTCACATCCTGCAGTCACCGACATCGGATTCACAGCTGTG 660
Qy        221 HisAlaLysTyrGlnSerProTrpLeuGlyThrIleGluSerValGluValTyrThrTrp 240
Db        661 CATGCTAAATACCAGAGTCCCTGGCTGGGAACCATTGAATCAGTTGAAGTCTACACCTGG 720
Qy        241 LeuAspAsnPheLeuLeuLeuMetLeuGlyGlyIleProTrpGlnAlaTyrPheGlnArg 260
Db        721 CTTGATAATTTTCTGTTATTGATGCTGGGTGGAATCCCATGGCAAGCCTACTTCCAGAGG 780
Qy        261 ValLeuSerSerSerSerAlaThrTyrAlaGlnValLeuSerPheLeuAlaAlaPheGly 280
Db        781 GTCCTCTCTTCATCCTCAGCCACCTATGCTCAGGTACTGTCCTTCCTGGCAGCTTTTGGG 840
Qy        281 CysLeuValMetAlaLeuProAlaIleCysIleGlyAlaIleGlyAlaSerThrAspTrp 300
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Qy        301 AsnGlnThrAlaTyrGlyTyrProAspProLysThrLysGluGluAlaAspMetIleLeu 320
Db        901 AACCAGACTGCCTACGGGTATCCAGATCCCAAGACTAAGGAGGAAGCAGACATGATTCTC 960
Qy        321 ProIleValLeuGlnTyrLeuCysProValTyrIleSerPhePheGlyLeuGlyAlaVal 340
Db        961 CCGATCGTTCTGCAGTACCTCTGCCCTGTGTACATCTCCTTCTTTGGGCTTGGTGCTGTT 1020
Qy        341 SerAlaAlaValMetSerSerAlaAspSerSerIleLeuSerAlaSerSerMetPheAla 360
Db       1021 TCAGCTGCTGTCATGTCCTCAGCTGACTCGTCCATCCTGTCGGCGAGTTCTATGTTTGCT 1080
Qy        361 ArgAsnIleTyrGlnLeuSerPheArgGlnAsnAlaSerAspLysGluIleValTrpVal 380
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Qy        381 MetArgIleThrValLeuValPheGlyAlaSerAlaThrAlaMetAlaLeuLeuThrLys 400
Db       1141 ATGAGGATCACTGTGCTTGTGTTCGGAGCATCTGCAACAGCCATGGCTTTGCTGACGAAG 1200
Qy        401 ThrValTyrGlyLeuTrpTyrLeuSerSerAspLeuValTyrIleIleIlePheProGln 420
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Qy        421 LeuLeuCysValLeuPheIleLysGlyThrAsnThrTyrGlyAlaValAlaGlyTyrIle 440
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Qy        441 PheGlyLeuPheLeuArgIleThrGlyGlyGluProTyrLeuTyrLeuGlnProLeuIle 460
Db       1321 TTTGGACTATTCCTGAGAATTACTGGAGGAGAGCCATATCTATACTTGCAGCCCTTAATC 1380
Qy        461 PheTyrProGlyTyrTyrSerAspLysAsnGlyIleTyrAsnGlnArgProProPheLys 480
Db       1381 TTCTACCCTGGTTATTACTCTGACAAGAATGGTATATACAATCAGAGGTTCCCATTTAAA 1440
Qy        481 ThrLeuSerMetValThrSerPhePheThrAsnIleCysValSerTyrLeuAlaLysTyr 500
Db       1441 ACTCTCTCCATGGTTACCTCATTCTTTACCAACATTTGTGTTTCTTATCTAGCCAAGTAT 1500
Qy        501 LeuPheGluSerGlyThrLeuProProLysLeuAspValPheAspAlaValValAlaArg 520
Db       1501 CTATTTGAAAGTGGAACCTTGCCTCCAAAATTAGATGTATTTGATGCTGTTGTCGCAAGG 1560
Qy        521 HisSerGluGluAsnMetAspLysThrIleLeuValArgAsnGluAsnIleLysLeuAsn 540
Db       1561 CACAGTGAAGAGAACATGGACAAGACCATTCTAGTCAGAAATGAAAATATCAAATTAAAT 1620
Qy        541 GluLeuAlaProValLysProArgGlnSerLeuThrLeuSerSerThrPheThrAsnLys 560
Db       1621 GAACTTGCACCTGTGAAACCTCGGCAGAGCCTAACCCTCAGTTCAACTTTCACCAATAAG 1680
Qy        561 GluAlaLeuLeuAspValAspSerSerProGluGlySerGlyThrGluAspAsnLeuGln 580
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RESULT 4
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LOCUS       E49872                1743 bp    DNA     linear   PAT 27-AUG-2002
DEFINITION  High-affinity choline transporter.
ACCESSION   E49872
VERSION     E49872.1  GI:22554903
KEYWORDS    JP 2001136976-A/4.
SOURCE      Mus sp.
  ORGANISM  Mus sp.
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Mammalia; Eutheria; Euarchontoglires; Glires; Rodentia;
            Sciurognathi; Muroidea; Muridae; Murinae; Mus.
REFERENCE   1  (bases 1 to 1743)
  AUTHORS   Haga,T. and Okuda,T.
  TITLE     High-affinity choline transporter
  JOURNAL   Patent: JP 2001136976-A 4 22-MAY-2001;
            SCIENCE & TECH AGENCY
COMMENT     OS   Mus sp. (mouse)
            PN   JP 2001136976-A/4
            PD   22-MAY-2001
            PF   27-DEC-1999 JP 1999368991
            PI   TATSUYA HAGA,TAKASHI OKUDA
            PC   C12N15/09,A01K67/027,A61K38/00,C07K14/47,C07K16/18,C07K19/00,
            PC   C12N5/10,
            PC   C12P21/02,C12P21/08,C12Q1/00,C12N15/00,A61K37/02,C12N5/00 CC
            FH   Key             Location/Qualifiers
            FT   CDS             (1). .(1743).
FEATURES             Location/Qualifiers
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                     /organism="Mus sp."
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ORIGIN

Alignment Scores:
Pred. No.:              0              Length:          1743
Score:                  2968.00        Matches:         576
Percent Similarity:     99.5%          Conservative:    1
Best Local Similarity:  99.3%          Mismatches:      3
Query Match:            99.2%          Indels:          0
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